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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,497	04/18/2006	Kim Borch	10525.204-US	6261
25908 7590 6905/2008 NOVOZYMES NORTH AMERICA, INC. 500 FIF'TH AVENUE			EXAMINER	
			HOBBS, LISA JOE	
SUITE 1600 NEW YORK, NY 10110			ART UNIT	PAPER NUMBER
- 1			1657	
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			09/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/576,497 BORCH ET AL. Office Action Summary Examiner Art Unit Lisa J. Hobbs 1657 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 09 June 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 12-28 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 12-28 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Interview Summary (PTO-413)
Paper No(s)/Mail Date. \_\_\_\_\_.

6) Other:

5) Notice of Informal Patent Application

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### DETAILED ACTION

### Claim Status

Claims 1-228 are active in the case. Claims 1-11 have been cancelled by the amendment of 09 June 2008.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Proelss (US 4,347,313). Proelss teaches a method for detecting lipolytic enzyme or amidase activity in a sample comprising incubating a sample with a polyunsaturated fatty acyl substrate with an amide or ester bond with subsequent incubation with lipoxygenase and then detecting the formation of the hydroperoxide (col. 2). He teaches a variety of polyunsaturated fatty acids (cols. 3 and 4, clms. 1 and 2) as well as colorimetric detection of the amount of peroxide produced in the second, lipoxygenase, step (col. 8, clms. 9-11).

Applicants argue that the various substrates specifically enumerated in claims 14-28 are not disclosed, thus those rejections have been withdrawn, however Proelss does disclose other natural or synthetic, simple or mixed tryglycerides (triacylglycerols) can be employed (col. 3, lines 66-68) and that R2 can be any fatty acid alkyl chain (col. 4, lines 42-44). Proelss

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specifically discloses using linoleic acid as a substrate for the

lipase/lipooxygenase/hydroperoxide reaction (col. 8, lines 10-40).

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior at are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue.
- Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 12-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proclss, Lal et al. (US 2003/0113846), and Bosjen et al. (US 2003/0175383) in view of Gay ((1999) Anal. Biochem. 273: 149-155). Proclss teaches a method of detecting lipolytic enzyme or amidase enzyme activity in a test sample, as described above, including a colorimetric assay, but does not teach the use of xylenol orange, specifically, in the color generation step.

Lal et al. teach that there are "[t]hree classes of lipid metabolism enzymes [which will be] discussed in further detail. The three classes are lipases, phospholipases and lipoxygenases" ([0011]). They teach that triglycerides are hydrolyzed to fatty acids and glycerol by lipases. Adipocytes contain lipases that break down stored triacylglycerols, releasing fatty acids for export to other tissues where they are required as fuel. Lipases are widely distributed in animals, plants, and prokarvotes. Triglyceride lipases (ExPASy ENZYME EC 3.1.1.3), also known as triacylglycerol lipases and tributyrases, hydrolyze the ester bond of triglycerides; gastric, hepatic, and pancreatic lipases hydrolyze lipoprotein triglycerides and phospholipids ([0013]), and that lipoprotein lipases (ExPASy ENZYME EC 3.1.1.34), also known as clearing factor lipases. diglyceride lipases, or diacylglycerol lipases, hydrolyze triglycerides and phospholipids present in circulating plasma lipoproteins, including chylomicrons, very low and intermediate density lipoproteins, and high-density lipoproteins ([0014]). They teach the Phospholipase A2 family, the Phospholipase B family ), also known as lysophospholipase, lecithinase B, or lysolecithinase, Phospholipase C and Phospholipase D families ([0015-0026]). As well, they teach lipoxygenases ([0027-0032]).

Bojsen et al. teach a general review including specific enzymes that act on galatolipids. It has been found that the enzyme of the invention may be particularly active against certain Art Unit: 1657

glycolipids such as for example galactolipids including digalactodiglyceride (DGDG) which is converted into digalactomonoglyceride (DGMG) that is an effective surfactant ([0065]). They teach that enzymes of the instant invention may be selected according to the present invention by screening the activity of enzymes on agar plates each containing either galactolipids, phospholipids, triglycerides or 1-monoglycerides as the substrate, although certain substrate usage is preferred ([0074]). They teach that in one embodiment of the method, at least one of the glycolipids, such as a galactolipid, including digalactosyldiglyceride (DGDG), and one of the phospholipids, such as phosphatidylcholine (PC), is a naturally occurring (or endogenous) lipid component ([0084]).

Gay et al. teach the use of xylenol orange (XO) in ferrous ion reactions with hyperperoxides for detection.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the references of Proelss, Lal et al., and Bosjen et al. with Gay et al. in order to obtain the instant invention as claimed. One would have been motivated to use any colorimetric assay components in the assay, as taught by Proelss (claims 9-11), but specifically XO since it is usable with chemically complex systems (p. 154). One would be motivated to detect and use any enzyme of the lipase/amidase/lipolytic family as taught by the prior art, especially since the prior art references teach a strong motivation for application in baking arts.

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### Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/ Primary Examiner Art Unit 1657